H2ONE- ethyl alcohol gel Zhejiang Guoyao Jingyue Aerosol Co., Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Ethyl Alcohol 75%

Purpose

Antiseptic

Uses To help reduce bacteria on the skin

Warnings

For external use only

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

FLAMMABLE, KEEP AWAY FROM FIRE

Stop Use and Ask a Doctor

Stop use and ask a doctor if rash or irritation or redness develops and lasts.

Keep out of reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

Other information

Store below 110F(43C) May discolor certain fabrics or surfaces

Inactive Ingredients

Aqua Glycerin Carbomer Aloe Vera Triethanolamine

Vitamin E

label



H2ONE

ethyl alcohol gel

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75	5742-006
Route of Administration	TOPICAL				
Active Ingredient/Active Moie	ety				
Ingred	ient Name		Basis of Strengt	h	Strength
ALCOHOL (UNII: 3K9958V90M) (ALC	OHOL - UNII:3K9958V90M)	A	ALCOHOL	75	mL in 100 mL
Inactive Ingredients					
Inactive Ingredients	Ingredient Name				Strength
Inactive Ingredients CARBOMER HOMOPOLYMER, UNSP	0	07FC)			Strength
	PECIFIED TYPE (UNII: 0 A5MM3	07FC)			Strength
CARBOMER HOMOPOLYMER, UNSP	PECIFIED TYPE (UNII: 0 A5MM3	07FC)			Strength
CARBOMER HO MO POLYMER, UNSP ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X	PECIFIED TYPE (UNII: 0 A5MM3	07FC)			Strength

GLYCERIN (UNII: PDC6A3C0OX)

]	Packaging				
\$	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75742-006- 01	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/06/2020		
2	NDC:75742-006- 02	375 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/06/2020		

3 NDC:75742-006- 03	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/06/2020			
4 NDC:75742-006- 04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/06/2020			
5 NDC:75742-006- 05	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/06/2020			
Marketing Information					
Marketing Categ	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
0 0					

Labeler - Zhejiang Guoyao Jingyue Aerosol Co., Ltd. (554529812)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Guoyao Jingyue Aerosol Co., Ltd.		554529812	manufacture(75742-006)

Revised: 7/2020

Zhejiang Guoyao Jingyue Aerosol Co., Ltd.